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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,680	01/24/2001	Asger Geppel	54337.000010	4425
7590 03/08/2006			EXAMINER	
Hunton & Williams LLP Intellectual Property Department 1900 K Street, NW Suite 1200 Washington, DC 20006			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1656	
DATE MAILED: 03/08/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/767,680	Applicant(s) GEPPEL ET AL	
	Examiner Chih-Min Kam	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-17 and 29-56 is/are pending in the application.
- 4a) Of the above claim(s) 29-33 and 53-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-17, 34-52 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>20051111</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/26/05</u> . | 6) <input type="checkbox"/> Other: _____. |

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DETAILED ACTION

1. The Request for Continued Examination (RCE) filed on January 19, 2006 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 4-17 and 29-56 are pending.

Applicants' amendment filed January 19, 2006 is acknowledged. Applicants' response and Declaration of Asger Geppel have been fully considered. Claims 4-17, 34-52 and 56 have been amended, and claims 1, 18-28 and 57 have been cancelled. Claims 29-33 and 53-55 are non-elected invention and withdrawn from consideration. Therefore, claims 4-17, 34-52 and 56 are examined.

Withdrawn Claim Rejections - 35 USC § 112

3. The previous rejection of claims 8, 9 and 34, under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment of the claim, and applicants' response at pages 10-11 in the amendment filed January 19, 2006.
4. The previous rejection of claims 1 and 57, under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicants' cancellation of the claim in the amendment filed January 19, 2006.

Withdrawn Claim Rejections - 35 USC § 103(a)

5. The previous rejection of claim 1, under 35 U.S.C. §103(a) as being unpatentable over Kaneko et al. (USPN 5,075,226), is withdrawn in view of applicants' cancellation of the claim in the amendment filed January 19, 2006.

Maintained - Claim Rejections - 35 USC § 112, first paragraph

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6. Previous rejection of Claims 4-17, 34-52 and 56 under 35 U.S.C. § 112, first paragraph, scope of enablement is maintained because the specification, while being enabling for lactic acid bacterial cells modified to contain at least 0.1 ppm haemin, does not reasonably provide enablement for lactic acid bacterial cells modified to contain at least 0.1 ppm of any porphyrin compound which includes iron (see paragraph 11 of the Office Action dated 11192004).

Applicant argues that the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The specification enables one of ordinary skill in the art to practice the claimed invention for all the reasons discussed during prosecution of this application, e.g., see pages 12-16 of the Response filed on February 2, 2004. In addition, a Declaration of Mr. Asger Geppel (Appendix A) states that a person of ordinary skill knows that different iron containing porphyrin compounds share the same chemical core structure (paragraphs 6 and 14); that haeme, haemin, cytochrome and hemoglobin are the examples of iron containing porphyrin compounds (paragraph 7); that “pure” haemin does not need to be used to make LAB cells which comprise an iron-containing porphyrin compound, but other haeme proteins from animal sources such as blood could also be used (paragraph 8); that since all types of iron containing porphyrin compounds are closely related (see specification, page 7, lines 14-16), thus, the invention should work for all types of iron containing porphyrin compounds; and that base on the specification, he would be able to make LAB cells comprising an iron containing porphyrin compound when cultured in fermentation medium containing any of the iron containing porphyrin compounds in any effective amount desirable, without undue experimentation (paragraph 11). Therefore, applicants request withdrawal of the rejection of claims 4-17, 34-52 and 56 (pages 11-14 of the response).

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Applicant's arguments and the Declaration of Mr. Asger Geppel have been fully considered but are not deemed persuasive for the following reasons.

While different iron containing porphyrin compounds share the same chemical core structure, and other iron containing porphyrin compounds such as haeme proteins from animal sources may be used for preparing modified LAB cells, as well as the use of porphyrin compounds is well known in the art to affect bacterial growth, the specification has not demonstrated the use of various iron containing porphyrin compounds such as haeme proteins in preparation of the claimed starter culture, which requires the retention of iron containing porphyrin compound to a specific extent (at least 0.1 ppm) in modified LAB cells as encompassed by the full scope of the claims, and this is not shown in the prior art. Furthermore, the state of the prior art is such that numerous iron containing porphyrin compounds are known, but all have different cellular association characteristics with different bacteria, therefore, it is wholly unpredictable how to achieve the containment of at least 0.1 ppm of iron containing porphyrin compounds other than those demonstrated, i.e., haemin in the specification and/or the art. Therefore, it requires undue experimentation to produce such cells to encompass the full scope of the claimed invention.

7. Previous rejection of Claim 5 under 35 U.S.C. § 112, first paragraph, scope of enablement is maintained, because the specification, while being enabling for lactic acid bacterial cells modified to contain at least 0.1 ppm cytochrome d when fermented under aerobic conditions, does not reasonably provide enablement for lactic acid bacterial cells modified when fermented under anaerobic conditions (see paragraph 12 of the Office Action dated 11/19/2004). Applicant's arguments have been fully considered but are not deemed persuasive for the

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following reasons. Applicant's arguments only reiterate those cited above and are not specific to the enablement issue of interest in the instant rejection. Thus, the response provided above by the Examiner is sufficient to rebut Applicant's arguments.

8. Previous rejection of Claims 8-9 under 35 U.S.C. § 112, first paragraph, enablement, as failing to comply with the enablement requirement is maintained (see paragraph 13 of the Office Action dated 11/19/2004). To make the cells claimed that will be effective when inoculated in a concentration of 10^7 cells/ml into low pasteurized skimmed milk having 8 ppm of dissolved oxygen would require undue experimentation. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant's arguments only reiterate those cited above and are not specific to the enablement issue of interest in the instant rejection. Thus, the response provided above by the Examiner is sufficient to rebut Applicant's arguments.

9. Previous rejection of Claim 9 under 35 U.S.C. § 112, first paragraph, scope of enablement is maintained (see paragraph 14 of the Office Action dated 11/19/2004), because the specification, while being enabling for lactic acid bacterial cells modified to consume at least 50% of dissolved oxygen with treatment under aerobic conditions, does not reasonably provide enablement for lactic acid bacterial cells modified when fermented under anaerobic conditions. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant's arguments only reiterate those cited above and are not specific to the enablement issue of interest in the instant rejection. Thus, the response provided above by the Examiner is sufficient to rebut Applicant's arguments.

10. Previous rejection of Claim 12 under 35 U.S.C. § 112, first paragraph, scope of

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enablement is maintained (see paragraph 15 of the Office Action dated 11/19/2004), because the specification, while being enabling for lactic acid bacterial cells modified to reduce LDH activity by at least 10% with treatment under aerobic conditions, does not reasonably provide enablement for lactic acid bacterial cells modified when fermented under anaerobic conditions. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant's arguments only reiterate those cited above and are not specific to the enablement issue of interest in the instant rejection. Thus, the response provided above by the Examiner is sufficient to rebut Applicant's arguments.

11. Previous rejection of Claim 16 under 35 U.S.C. § 112, first paragraph, scope of enablement is maintained (see paragraph 16 of the Office Action dated 11/19/2004), because the specification, while being enabling for lactic acid bacterial cells modified to contain at least 0.1 ppm cytochrome d using mixed lactic acid bacterial strains grown aerobically, does not reasonably provide enablement for lactic acid bacterial cells modified to contain at least 0.1 ppm of any iron containing porphyrin compound using pure strains. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant's arguments only reiterate those cited above and are not specific to the enablement issue of interest in the instant rejection. Thus, the response provided above by the Examiner is sufficient to rebut Applicant's arguments.

12. Previous rejection of Claims 40-42 under 35 U.S.C. § 112, first paragraph, enablement, as failing to comply with the enablement requirement is maintained (see paragraph 17 of the Office Action dated 11/19/2004). The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with

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which it is most nearly connected, to make and/or use the invention at “at least 60 ppm” or higher of an iron containing porphyrin compound. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant's arguments only reiterate those cited above and are not specific to the enablement issue of interest in the instant rejection. Thus, the response provided above by the Examiner is sufficient to rebut Applicant's arguments.

13. Previous rejection of Claims 45-47 under 35 U.S.C. § 112, first paragraph, enablement, as failing to comply with the enablement requirement is maintained (see paragraph 18 of the Office Action dated 11/19/2004). The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention at “at least 40 ppm” or higher of a cytochrome. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant's arguments only reiterate those cited above and are not specific to the enablement issue of interest in the instant rejection. Thus, the response provided above by the Examiner is sufficient to rebut Applicant's arguments.

14. Previous rejection of Claims 48-52 under 35 U.S.C. § 112, first paragraph, scope of enablement is maintained (see paragraph 19 of the Office Action dated 11/19/2004), because the specification, while being enabling for cells that, after having been treated with 10 mg/L haemin and inoculated into milk can reduce the amount of dissolved oxygen by about 35% per hour does not reasonably provide enablement for cells otherwise treated that reduce the amount of dissolved oxygen at greater than 35% per hour. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant's arguments only

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reiterate those cited above and are not specific to the enablement issue of interest in the instant rejection. Thus, the response provided above by the Examiner is sufficient to rebut Applicant's arguments.

Maintained - Claim Rejections - 35 USC § 103(a)

15. Previous rejection of Claims 4-7, 10-17, 35-39, 43, 44, 48, and 49 under 35 U.S.C. § 103(a) as being unpatentable over Kaneko *et al.* (USPN 5,075,226) is maintained (see paragraph 19 of the Office Action dated 11/19/2004). Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that the claims have been amended to a starter culture composition comprising at least one modified lactic acid bacterial cell that comprises at least 0.1 ppm on a dry matter basis of a porphyrin compound which includes iron. A “starter” culture has a defined or recognized meaning in the art (see the definition in McGraw-Hill Dictionary of Scientific and Technical Terms, 5th Ed., Appendix C). The bacterial cultures as described by Kaneko *et al.* are used to produce diacetyl and acetoin, and there is no discussion or contemplation of the isolation or harvesting of these bacteria from the end products following completion of the fermentation process for any use, much less as an isolated starter culture (see Examples 1-5). As a result, not all of the claim elements are taught or suggested (pages 14-15 of the response).

Applicants' arguments are not found persuasive because Kaneko *et al.* teach culturing lactic acid bacteria, aerobically, in haemin (MW 327 g/mol) at a concentration of 0.1-500 μ M (column 3, lines 21-24; Examples; 500 μ M is equivalent to 327 mg/L haemin), and using concentration of 1-2% in inoculation as a starter culture to produce diacetyl and acetoin (see column 5; Example 1), and it is suggested that the culture solution or a concentrate thereof is

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used to increase or improve the flavor of foods (column 5, lines 6-10). Thus, it would be expected that the culture solution taught by Kaneko *et al.* would be isolated for subsequent use to improve the flavor of foods, which meets the elements recited in the claims.

Conclusion

16. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



**CHIH-MIN KAM
PATENT EXAMINER**

CMK

March 3, 2006